DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 12-796/S-048

JUN 2 4 1998

A.H. Robins Company,
Attention: Ms. Diane Mitrione
170 North Radnor-Chester Road
St. Davids, PA 19087

Dear Ms. Mltrione:

Please refer to your March 12, 1998 supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Quinidex (quinidine sulfate extended-release tablets) Extentabs, 300 mg.

The supplemental application provides for final printed labeling revised under **PRECAUTIONS/Drug Interactions** for addition of a statement regarding a drug interaction between quinidine and diltiazem. In addition, information regarding Quinidex Extentabs' compliance with the USP Drug Release Test has been added to the **DESCRIPTION** section of the labeling.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the final printed labeling included with your March 12, 1998 submission. Accordingly, the supplemental application is approved effective on the date of this letter.

At the time of your next printing, please change the statement "Caution: Federal law prohibits dispensing without prescription" under **HOW SUPPLIED** to "Rx only."

In addition, please consider revising the storage statement as follows:

> Store at 25°C (77°F); excursion permitted to 15°-30°C
> (59°-86°F). (See USP Controlled Room Temperature)

A supplemental application need not be submitted to implement these changes. They should, however, be reported in the next annual report.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.